REMARKS

Claims 1, 7 and 10 have been amended to delete fragment language. No new matter is added by these amendments, and entry of the amendments is requested.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 1, 2, 13, 17 and 18) drawn to polypeptides comprising the amino acid sequence of SEQ ID NO:1, pharmaceutical compositions, methods of treating or preventing a nuerological disorder, and methods of treating or preventing a cardiovascular disorder.

Group II (claims 1, 2, 13, 17 and 18) drawn to polypeptides comprising the amino acid sequence of SEQ ID NO:2, pharmaceutical compositions, methods of treating or preventing a nuerological disorder, and methods of treating or preventing a cardiovascular disorder.

Group III (claims 3-12, 20 and 21) drawn to polynucleotides encoding polypeptides comprising the amino acid sequence of SEQ ID NO:1, fragments thereof, vectors, host cells, methods of producing a polypeptide, and methods of detecting a polynucleotide.

Group IV (claims 3-12, 20 and 21) drawn to polynucleotides encoding polypeptides comprising the amino acid sequence of SEQ ID NO:2, fragments thereof, vectors, host cells, methods of producing a polypeptide, and methods of detecting a polynucleotide.

Group V (claim 15) drawn to an agonist of a polypeptide comprising the amino acid of SEQ ID NO:1.

Group VI (claim 15) drawn to an agonist of a polypeptide comprising the amino acid of SEQ ID NO:2.

Group VII (claims 16 and 19) drawn to an antagonist of a polypeptide comprising the amino acid of SEQ ID NO:1.

Group VIII (claims 16 and 19) drawn to an antagonist of a polypeptide comprising the amino acid of SEQ ID NO:2.

Applicants hereby elect, with traverse, to prosecute Group I, which includes and is drawn to Claims 1, 2, 13, 17 and 18. Applicants traverse both the restriction requirement and the obligation to elect a single sequence for prosecution for at least the following reasons.

I. The unity of invention standard ***must*** be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....
>
> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

The present application, filed under 35 U.S.C. §371 is a national-stage application; the Examiner is therefore **required** to apply the unity of invention standard.

II. Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

A. Unity of Invention is accepted as between claims to polypeptide sequences and claims to the polynucleotide sequences which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims to polypeptide sequences and claims to polynucleotide sequences encoding those polypeptides. Those Examples are cited in MPEP section 1893.03(d) at page 1800-149, column 2 ("[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions...")

Thus, in the present case, unity of invention exists at least as between claims drawn to polypeptide sequences SEQ ID NO:1 or 2 (*i.e.*, claims 1, 2, 13, 17 and 18) of Groups I-II and as to claims drawn to polynucleotide sequences which encode those polypeptides, SEQ ID NOs:3 or

4, respectively (*i.e.,* claims 3-7 and 11) of Groups III-IV (claims 3-12, 20 and 21).

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-13, 17-18, and 20-21, relative to SEQ ID NOs:1 and 3 and examine those claims in a single application.

B. Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention....

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

In the present case, claims 2-6, 10-11, and 13, all of which depend from claim 1, are all directed to compositions of matter, *i.e.,* to products. Similarly, claims 8 and 9 which depend from claim 7, are all directed to compositions of matter, *i.e.,* to products. All of these claims contain all of the features of the independent claim. Further, as discussed above, there is unity of invention between claim 1 and claim 7. Finally, both claim 1 and claim 7 avoid the prior art, as discussed below.

Thus, it is improper to restrict claims 1, 2 and 13 from claims 3-11, as the Examiner has done. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to the composition of matter claims related to SEQ ID NOs:1 and 3, and that at least those claims be considered together in a single application.

III. Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The claimed polypeptide sequences and the claimed polynucleotide sequences encoding them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

A. The claimed polypeptide sequences, and the claimed polynucleotide sequences encoding those polypeptide sequences, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

Applicants' claims recite *inter alia* the polypeptides SEQ ID NO:1-2, and polynucleotides encoding those polypeptides, which sequences include the polynucleotide sequences SEQ ID NO:3-4. Applicants respectfully submit that the claimed polypeptide sequences SEQ ID NO:1-2, and the claimed polynucleotide sequences encoding them, are corresponding technical

features, given that the former are encoded by the latter, and conversely, the latter encode the former.

Further, the claimed polypeptide and corresponding polynucleotide sequences are common to all of Applicant's claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the claimed sequences.

Moreover, the claimed polypeptide and corresponding polynucleotide sequences serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims (claims1 -11, and 13-16) are drawn to either the polypeptide and polynucleotide sequences themselves (claims 1 and 2, drawn to polypeptide sequences, and claims 3-8, drawn to polynucleotide sequences), to compositions of matter which comprise the sequences as one element (claims 7-8, drawn to an expression vector and transformed cells, respectively, and claim 13, drawn to a pharmaceutical composition), or to compositions of matter wherein the claimed sequences functionally limit the claimed subject matter (claim 14, drawn to an antibody which specifically binds a polypeptide of claim 1, claim 15 drawn to an agonist of the polypeptide of claim 1, and claim 16 drawn to an antagonist of the polypeptide of claim 1).

In Applicants' method claims (claims 12 and 17-21), the claimed sequences serve as either the product of the claimed method (claim 12, drawn to a method of polypeptide production) and/or as a reagent for performing the method (claims 17-21, drawn, respectively, to methods of treating or preventing a neurological disorder, cardiovascular disorder, or a cancer, or a method of detecting the claimed polynucleotide in a sample.)

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

B. <u>The claimed polypeptide and polynucleotide sequences define the contribution made by each of Applicants' claims over the prior art.</u>

Contrary to the Examiner's assertion, the polypeptide and polynucleotide sequences claimed by Applicants are themselves contributions over the prior art, and they therefore define the contribution made over the prior art by all of Applicants' other claims.

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

At page 3, first paragraph of the Restriction Requirement, the Examiner alleges that the inventions of Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature that would possibly unite all of the separate inventions is either, in the case of groups I, III, V and VI, the polypeptides comprising SEQ ID NO:1, or comprising fragments of SEQ ID NO:1; or, in the case if groups II, IV, VI and VIII, the polypeptides comprising SEQ ID NO:2, or comprising fragments of SEQ ID NO:2. However, neither of these products is a special technical feature as defined in PCT Rule 13.2, because the products of either the polypeptide comprising a fragment of SEQ ID NO:1, or the polypeptide comprising a fragment of SEQ ID NO:2 are obvious over the prior art as evidenced by (citations of various Database EMEST NOs.), which teach polynucleotides encoding polypeptides that comprise fragments of either SEQ ID NO:1 or SEQ ID NO:2.

Applicants submit that the claims have been amended to delete the recitation of fragments of SEQ ID NO:1 or SEQ ID NO:2, or polynucleotides encoding fragments of SEQ ID NO:1 or SEQ ID NO:2. Applicants point out that it is those polypeptide sequences and/or those corresponding polynucleotide sequences in their ***entire*** form which provide the "common or corresponding special technical feature" linking all of the claims to form a single general inventive concept.

Applicants respectfully point out that the full-length polypeptide and corresponding full-length polynucleotide sequences recited in claims 1 and 7 in their current form, and the claims dependent thereon, are not anticipated by the sequences described by the cited reference. First, none of the full-length polypeptide or polynucleotide sequences recited in claim 1 or claim 7 as they are currently pending are explicitly disclosed by the cited references. Moreover, even assuming for purposes of argument that the reference sequences disclose polypeptide fragments which exhibit sequence identity with *fragments* of SEQ ID NO:1 or SEQ ID NO:2, neither SEQ ID NO:1 or SEQ ID NO:2 themselves, nor any polynucleotide sequence which encodes SEQ ID NO:1 or SEQ ID NO:2, can be anticipated by those fragments. Therefore, the contribution over

the prior art represented by the full-length polypeptide and polynucleotide sequences is not negated by the cited references.

In sum, the claimed polypeptide sequences and the claimed polynucleotide sequences which encode them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept with respect to SEQ ID NOs:1 and 3, and SEQ ID NOs:2 and 4, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application. Withdrawal of the restriction requirement and examination of all claims with respect to SEQ ID NOs:1 and 3 in the present case is therefore respectfully requested.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

CONCLUSION

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

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